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Transfer of a Premarket Notification (510(k)) Clearance – Questions and Answers

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Guidance for Industry and Food and Drug Administration Staff

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For questions about this document regarding CDRH-regulated devices, contact the Premarket Notification (510(k)) Staff at 301-796-5640.

For questions about this document regarding CBER-regulated devices, contact CBER at 800-835-4709 or 240-402-8010, or by email at industry.biologics@fda.hhs.gov.

For general questions regarding FDA's electronic device registration and listing system, please contact Registration and Listing at reglist@cdrh.fda.gov or 301-796-7400, Option 1.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to https://www.regulations.gov. Submit written comments to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852-1740. Identify all comments with the docket number FDA-2024-D-1528. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and Food and Drug Administration Staff

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction

This guidance provides information on the most frequently asked questions regarding the transfer or sale of a 510(k) clearance from one 510(k) holder to another. Under section 510(k) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and its implementing regulations, any person required to register under section 510 / 21 CFR 807.20 must generally submit a premarket notification submission, or "510(k)," if the device is being introduced into commercial distribution for the first time, or the device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or modified in design, components, method of manufacture, or intended use.[1]

This guidance discusses when the sale or transfer of a 510(k) would not require the new holder of a 510(k) to submit a new 510(k) under applicable law, as well as circumstances under which entities must use the FDA-assigned premarket submission number of the cleared 510(k) when listing their device.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but

[1] See section 510(k) of the FD&C Act; see also section 513(i) of the FD&C Act, 21 CFR sections 807.20, 807.81(a), and FDA's guidance documents "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," "Deciding When to Submit a 510(k) for a Change to an Existing Device," and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."

not required.

II. Scope

This guidance applies to both the previous and the new holder of a 510(k) after the 510(k) clearance for a specific device is sold or transferred from one person to another.

III. Definitions

For purposes of this guidance, we will use the following definitions:

510(k) clearance: FDA's order declaring the subject device to be substantially equivalent to a legally marketed predicate device.[2]

510(k) holder: The singular person who possesses the 510(k) clearance for a device. The 510(k) holder may be a manufacturer, which may be a specifications developer.

Contract manufacturer: A person who manufactures a device for or on behalf of a specifications developer or any other person.[3]

Contract sterilizer: A person who sterilizes a device for or on behalf of a specifications developer or any other person.[4]

Initial importer: Any importer who furthers the marketing of a device from a foreign manufacturer to the person who makes final delivery or sale of the device to the ultimate consumer or user, but does not repackage, or otherwise change the container, wrapper, or labeling of the device or device package.[5]

Labeler: (1) Any person who causes a label to be applied to a device with the intent that the device will be commercially distributed without any intended subsequent replacement or modification of the label; and (2) Any person who causes the label of a device to be replaced or modified with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label, except that the addition of the name of, and contact information for, a person who distributes the device, without making any other changes to the label, is not a modification for the purposes of determining whether a person is a labeler.[6]

Manufacturer: A person who makes by chemical, physical, biological, or other procedures, any article that meets the definition of "device" in section 201(h) of the FD&C Act.[7]

Person: Includes individuals, partnerships, corporations, and associations as defined under

[2] See 21 CFR 807.100(a)(1).
[3] See 21 CFR 807.20(a)(2).
[4] See id.
[5] 21 CFR 807.3(g).
[6] See 21 CFR 801.3.
[7] See 21 CFR 807.3(d).

section 201(e) of the FD&C Act.

Relabeler: A person who changes the content of the labeling from that supplied from the original manufacturer for distribution under the establishment's own name. A relabeler does not include establishments that add their own name to but otherwise do not change the original labeling.

Remanufacturer: A person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use.[8]

Repackager: A person who packages finished devices from bulk or repackages devices made by a manufacturer into different containers. A repackager does not include an entity that only places finished packaged devices into shipping containers for transportation.

Reprocessor of single-use devices: A person who performs additional processing and manufacturing on a single-use device that was previously used on a patient for the purpose of an additional single use on a patient.[9]

Specifications developer: A person who initiates specifications for a device that is manufactured by a second party for subsequent commercial distribution by the person initiating specifications.[10]

IV. Questions and Answers

1. Who needs to register and list?

An owner or operator of an establishment who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device intended for human use is generally required to register the establishment and submit listing information for all devices in commercial distribution.[11]

2. Who needs to submit a 510(k) to FDA?

[8] See 21 CFR 820.3(a); also see FDA's guidance, "Remanufacturing of Medical Devices."
[9] See section 201(ll) of the FD&C Act. See also section 510(o) of the FD&C Act and 21 CFR 807.20(a)(4).
[10] See 21 CFR 807.3(d)(3). See also 21 CFR 807.20(a)(1).
[11] 21 CFR 807.20(a). See sections 510(b) and 510(j) of the FD&C Act. Any foreign establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a device that is imported or offered for import into the United States is required to register and list in conformance with the procedures in 21 CFR 807.40, 21 CFR 807.41, and subpart B of 21 CFR Part 807. See section 510(i) of the FD&C Act. The registration requirement does not apply to owners or operators that are exempt under section 510(g) of the FD&C Act or subpart D of 21 CFR Part 807. For more information about the registration and listing process, see FDA's website, "Device Registration and Listing."

You generally are required to submit a 510(k) if your device is subject to the requirements arising under section 510(k) of the FD&C Act[12] and you are a manufacturer, [13] including a:

a. Finished device manufacturer that manufactures a device according to its own specifications and markets it in the U.S.

b. Manufacturer of components or accessories to finished devices that are ready to be used for any intended health-related purpose and packaged or labeled for commercial distribution for such health-related purpose, or devices which of necessity must be further processed by a licensed practitioner or other qualified person to meet the needs of a particular patient.[14]

c. Remanufacturer.

d. Reprocessor of single-use devices.

e. Specifications developer.[15]

You may also be required to submit a 510(k) if you currently have a device in commercial distribution or are reintroducing it into commercial distribution and the device is about to be significantly changed or modified in design, components, method of manufacture, or intended use.[16]

Once FDA finds your device to be substantially equivalent to a legally marketed device, you become the "510(k) holder" and will be listed as the "applicant" in the 510(k) Premarket Notifications Database.[17]

3. When does a manufacturer need to submit a 510(k)?

Under section 510(k) of the FD&C Act, persons who are required to register their establishment must generally submit a 510(k) to FDA at least 90 days before proposing to begin the introduction or delivery for introduction into interstate commerce for commercial distribution of a device intended for human use if the device is being introduced into commercial distribution for the first time, or if the device is one that the person currently has in commercial distribution or is reintroducing into commercial distribution, but that is about to be significantly changed or

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[12] Any person required to register under 21 CFR 807.20 who plans to introduce a device into commercial distribution for the first time must, per 21 CFR 807.81(a)(2), submit a 510(k) if that device is not exempt from premarket notification requirements. See 21 CFR 807.81, and FDA's guidance documents "Deciding When to Submit a 510(k) for a Change to an Existing Device," and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device." See also questions 3 through 9 of this guidance.

[13] A manufacturer can be either domestic or foreign. See 21 CFR 807.20(a) and 21 CFR 807.40(a).

[14] 21 CFR 807.20(a), (a)(6); see FDA's website "Premarket Notification 510(k)."

[15] The specifications developer, subject to the requirements arising under section 510(k), as opposed to the contract manufacturer, must submit the 510(k).

[16] See 21 CFR 807.81(a)(3); also see FDA's guidance documents "Deciding When to Submit a 510(k) for a Change to an Existing Device" and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."

[17] The person listed as the applicant does not change even if the 510(k) is transferred. See FDA's 510(k) Premarket Notification Database.

modified in design, components, method of manufacture, or intended use.[18] See questions 1 and 6 for more information about registration.

4. I obtained a 510(k) clearance from another company (via transfer, sale, etc.). Do I need to submit a new 510(k)?

When a 510(k) clearance for a specific device is sold or transferred from one person to another and the device is not significantly changed or modified in design, components, method of manufacture, or intended use,[19] the new 510(k) holder does not need to submit a new 510(k), since the new 510(k) holder would not be proposing "to begin the introduction or delivery for introduction into interstate commerce for commercial distribution" of a device.[20] See question 10 for more details about the obligations of the 510(k) holder regarding a transfer or sale of a 510(k).

5. What are the listing requirements for a new 510(k) holder?

When a 510(k) clearance for a specific device is sold or transferred from one person to another, if the new 510(k) holder is engaged in any of the activities requiring listing, 21 CFR 807.25 requires the new 510(k) holder to list the device in FDA's electronic device registration and listing system.[21] The system assigns a new unique listing number when the new 510(k) holder creates the listing.[22]

For further information about registering and listing, see the webpage, "How to Register and List."

6. When should a new 510(k) holder register and list?

The new 510(k) holder must, if not previously entered into an operation described in 21 CFR 807.20(a), register within 30 days after entering into such an operation and submit device listing information, including the FDA-assigned 510(k) premarket notification submission number of the cleared device,[23] at that time.[24]

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[18] 21 CFR 807.81(a); also see FD&C Act section 513(i). Note that a 510(k) is not required for a device for which a premarket approval application under section 515 of the FD&C Act, or for which a petition to reclassify under section 513(f)(2) of the FD&C Act, is pending before FDA, or for which there is a predetermined change control plan (PCCP) cleared under section 515C of the FD&C Act, provided that the change is consistent with the PCCP. 21 CFR 807.81(b)(1).

[19] For discussion about changes or modifications to existing devices that could require submission of a new 510(k), see FDA's guidance documents "Deciding When to Submit a 510(k) for a Change to an Existing Device" and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."

[20] See 21 CFR 807.81(a) and 42 FR 42523 (August 23, 1977); see also 21 CFR 807.85(b)(2).

[21] 21 CFR 807.25. If new 510(k) holders have been granted a waiver from electronic submission in accordance with 21 CFR 807.21(b), they must submit the required device listing information in paper form using the procedures set forth in 21 CFR 807.34. 21 CFR 807.25(g).

[22] When a new listing number is created, labelers must also update the Global Unique Device Identification Database (GUDID) record with the new listing number. 21 CFR 830.330(b).

[23] 21 CFR 807.25(g)(4).

[24] 21 CFR 807.22(a). See 21 CFR 807.22 for other registration and listing timing requirements.

The new 510(k) holder must, every fiscal year, during the period beginning on October 1 and ending on December 31, report any new device listings that were not previously reported, including any devices that are the subject of the newly acquired 510(k) clearances.[25] Changes to listing information may also be made at other times, such as when a device is introduced into commercial distribution, when a change is made to a previously listed device, or when a previously listed device is removed from commercial distribution.[26]

Importantly, FDA may utilize its electronic device registration and listing system to identify any person who is engaged in the manufacture, preparation, propagation, compounding, assembly, or processing of a device in its postmarket surveillance efforts, including, for example, to timely notify a firm of the need to begin immediately a recall of a device that presents a risk of illness or injury.[27]

7. Which cleared 510(k) premarket notification submission number must the new 510(k) holder enter in FDA's electronic device registration and listing system?

Each device listing for a 510(k)-cleared device requires inclusion of the FDA-assigned premarket submission number of the cleared 510(k).[28]

If the device is not significantly changed or modified in design, components, method of manufacture, or intended use,[29] the new 510(k) holder must enter the original FDA-assigned premarket submission number unless submitting a new 510(k), in which case the new 510(k) holder would supply the new FDA-assigned premarket submission number, in **FDA's electronic device registration and listing system**.[30]

If the new 510(k) holder has significantly changed or modified the device in design, components, method of manufacture, or intended use, the new 510(k) holder must generally submit a new 510(k)[31] and, when listing following clearance of the new 510(k), would enter the new FDA-assigned premarket submission number in **FDA's electronic device registration and listing system**.[32]

8. Can a device have simultaneous 510(k) holders?

No. FDA considers there to be a single "510(k) holder" (e.g., an individual, partnership, corporation, association) for a device at a time. Under section 510(k), "[e]ach person who is required to register" and who "proposes to begin the introduction or delivery for introduction

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[25] 21 CFR 807.22(b)(3).
[26] 21 CFR 807.22(b)(4).
[27] See 21 CFR 7.45(a), (b).
[28] 21 CFR 807.25(g)(4).
[29] For discussion about changes or modifications to existing devices that could require submission of a new 510(k), see FDA's guidance documents "Deciding When to Submit a 510(k) for a Change to an Existing Device" and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device."
[30] The new 510(k) holder need not submit a new 510(k) because the new 510(k) holder is not proposing "to begin the introduction or delivery for introduction into interstate commerce for commercial distribution" of the device. See 21 CFR 807.81(a) and 42 FR 42523 (August 23, 1977); see also 21 CFR 807.85(b)(2) (applies to those distributors and repackagers who are exempt from submitting a 510(k) if it was filed by another person).
[31] 21 CFR 807.81(a)(3).
[32] 21 CFR 807.25(g)(4).

into interstate commerce for commercial distribution of a device intended for human use" must generally submit a report pursuant to section 510(k).[33] Having one 510(k) holder per device, among other things, helps to ensure compliance with applicable legal requirements, allows for appropriate tracking of signals and adverse events associated with devices, and facilitates communication between sponsors and FDA.[34]

When a 510(k) is transferred or sold, the new 510(k) holder must create a new listing to reflect the transfer if introducing the device into commercial distribution.[35] (See the answer to question 5 for more details.) Such listing enables FDA to identify the current 510(k) holder. A previous 510(k) holder that ceases to perform an activity on or to the device that had previously been identified on the device listing (for example, manufacturing the device) must update such device listing.[36] Also, a 510(k) holder who discontinues commercial distribution of a device must discontinue the device listing.[37]

We note that this guidance is not intended to limit a person's ability to transfer a 510(k) or engage in business arrangements with other persons. We understand that there may be complicated business arrangements associated with the manufacture and distribution of certain 510(k)-cleared devices. Please see question 9 for more information about examples of other entities that could potentially have contractual relationships with the 510(k) holder and who must use the FDA-assigned premarket submission number of the cleared 510(k) if required to list the device. If you have any case-specific questions concerning the designation of the 510(k) holder for a device, please contact the Premarket Notification (510(k)) Staff at 301-796-5640.

9. Who can use a 510(k) holder's 510(k) number to list a device?

Anyone who is required to list a cleared device, including contract manufacturers, contract sterilizers, repackagers, and relabelers, is required to use the FDA-assigned premarket submission number of the cleared 510(k) to list the device.[38] The 510(k) holder is also responsible for complying with applicable requirements arising under the FD&C Act.

Initial importers may fulfill their listing obligation for a device for which they did not initiate or develop the specifications for the device or repackage or relabel the device by submitting the name and address of the manufacturer.[39]

10. Is there other information a new 510(k) holder may need to submit to FDA?

The transfer or sale of a 510(k) clearance may require label updates, including revisions to the name and place of business of the manufacturer, packer, or distributor.[40] Labelers must also ensure that, in general, the label of every medical device and every device package bears a

[33] Section 510(k) of the FD&C Act. See also 21 CFR 807.81(a)(2) and 807.85(b)(2).
[34] The FD&C Act and its implementing regulations may apply regardless of whether someone is the 510(k) holder.
[35] See 21 CFR 807.28(b)(2).
[36] 21 CFR 807.28(a).
[37] 21 CFR 807.28(d).
[38] 21 CFR 807.25(g)(4).
[39] 21 CFR 807.20(a)(5).
[40] 21 CFR 801.1(a).

unique device identifier (UDI).[41] In addition, when a 510(k) clearance for a specific device is sold or transferred from one person to another, the labeler must submit an update to the information required by 21 CFR 830.310 by using the Global Unique Device Identification Database (GUDID) if such information (for example, the name of the labeler) has changed.[42] For more information about GUDID requirements, see the "Global Unique Device Identification Database (GUDID)" guidance and FDA's webpage, "Global Unique Device Identification Database (GUDID)."

If you fail to register, list, update GUDID information, or submit a marketing application when required, your device may be considered adulterated and/or misbranded.[43]

See the website, "FDA Industry Systems," for information about other FDA databases, such as the CDRH Export Certification Application and Tracking System (CECATS).

11. Who must update information about a 510(k) transfer or sale?

FDA commonly receives notifications from individuals that a 510(k) clearance has been transferred to that individual from a previous 510(k) holder, and asking FDA to update the information in the registration and listing databases. However, it is the responsibility of the owner or operator of the establishment[44] to ensure that it is meeting the registration and listing requirements of the FD&C Act. FDA is not required to update registration or listing information in response to such notifications.

12. How should I obtain copies of 510(k) records?

An entity wishing to have a copy of any 510(k) records may ask the prior owner for a copy of all documents, or may submit a Freedom of Information Act (FOIA) request.[45] Additionally, CDRH posts 510(k) records previously released to the public through FOIA requests in the 510(k) database.

[41] 21 CFR Part 801, subpart B and 21 CFR Part 830; see FDA's guidance document, "Unique Device Identification System: Form and Content of the Unique Device Identifier (UDI)."
[42] 21 CFR 830.310(a)(1); 830.330(b) ("The labeler of a device shall submit to FDA an update to the information required by § 830.310 whenever the information changes. The updated information must be submitted no later than the date a device is first labeled with the changed information. If the information does not appear on the label of a device, the updated information must be submitted within 10 business days of the change.").
[43] See sections 501(f)(1)(B), 502(a)(1), 502(o), and 502(t)(2) of the FD&C Act.
[44] See 21 CFR 807.20(a).
[45] For more information, see FDA's webpage, "CDRH FOIA: How to Get Records from CDRH."

Guidance History	Date	Description
Level 1 Final Guidance	November 2026	See Notice of Availability for more information.**
Level 1 Draft Guidance	June 2025	See Notice of Availability for more information.**

**The Notice of Availability is accessible via the Search for FDA Guidance Documents webpage